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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,174	12/04/2001	Simon Cawley	3397.1	2912

22886 7590 02/11/2004

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EXAMINER

CLOW, LORI A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/006,174	Applicant(s) CAWLEY ET AL.	
	Examiner Lori A. Clow, Ph.D.	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 9-16 and 25-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 17-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/23/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election without traverse of Group I, in the paper mailed 26 November 2003 is acknowledged.

Claims 1-32 are currently pending. Claims 9-16 and 25-32 have been withdrawn for being drawn to a nonelected invention. Applicant is reminded that a complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Information Disclosure Statement

The Information Disclosure Statement filed 23 June 2003 has been entered and considered. An initialed copy of the form PTO-1449 is enclosed with this action.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See, for example, page 14, line 14.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

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The method and system of claims 1-8 for determining whether a biological sequence has a certain characteristic comprising obtaining evidence and determining a characteristic based upon a Bayesian analysis is merely a mathematical manipulation of data. There is nothing in the claimed subject matter to indicate the usefulness of such manipulation of biological sequence data.

MPEP 2106: "For such subject matter to be statutory, the claimed process must be limited to a practical application of the abstract idea or mathematical algorithm in the technological arts. See *Alappat*, 33 F.3d at 1543, 31 USPQ2d at 1556-57 (quoting *Diamond v. Diehr*, 450 U.S. at 192, 209 USPQ at 10). See also *Alappat* 33 F.3d at 1569, 31 USPQ2d at 1578-79 (Newman, J., concurring) ("unpatentability of the principle does not defeat patentability of its practical applications") (citing *O'Reilly v. Morse*, 56 U.S. (15 How.) at 114-19). A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible, and useful result; i.e., the method recites a step or act of producing something that is concrete, tangible, and useful. See *AT&T*, 172 F.3d at 1358, 50 USPQ2d at 1452. Likewise, a machine claim is statutory when the machine, as claimed, produces a concrete, tangible, and useful result (as in *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601) and /or when a specific machine is being claimed (as in *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557 (in banc))."

The instant claims are not concrete, tangible, and useful as one would not know what characteristic was being determined or what evidence was being gathered in order to determine the characteristic. Without such knowledge, the instant claims are not immediately useful to one of skill in the art and would require further research in order to determine the various parameters of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 17-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 17 recite “a biological sequence has certain characteristic”. It is unclear what characteristic is intended. Does this refer to a sequence of a certain length, a certain function, a certain homology to another known sequence?

Claims 1 and 17 recite “obtaining a plurality of evidence about the characteristic”. This is vague and indefinite as it is unclear what kinds of evidence, other than sequence annotation, is being obtained. Furthermore, sequence annotation can comprise numerous parameters, such as sequence length, sequence homology information, and other such information. There is nothing in the claims that make clear what is being evidenced.

Claims 2 and 18 recite “defining the prior probability of the biological sequence”. There is insufficient antecedent basis in the claim for “the prior probability”. Clarification is requested.

Claims 2 and 18 recite “evidence assuming the hypothesis is true”. There is insufficient antecedent basis in the claim for “the hypothesis”. Clarification is requested.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Ma et al. (International Journal on Artificial Intelligence Tools (1999), pages 1-19).

The instant claims are drawn to a computerized method and system for determining whether a biological sequence has a certain characteristic comprising obtaining evidence about the characteristic and determining the characteristic using Bayesian analysis.

In regard to claims 1-3 and 17-19, Ma et al. teach identification of promoters in unlabeled DNA sequences by classification using Bayesian networks (see abstract). The uncertainty about each neural network in this approach is taken into account by weighting the neural network by its posterior probability. The Bayesian neural network controls the model complexity to avoid the overfitting problem (page 1, line 31-page 2, lines 1-3). An approach to the method is to use a high-level features extracted from biosequences (annotations). The features should be relevant and biologically meaningful (page 2, paragraph 5).

The description of a Bayesian network, at page 9, section 3.1, describes the model consisting of a set of parameters viewed as random variables. A “prior”, a “likelihood” and a “posterior probability” are described which ultimately define Bayes Rule and meet the all of the limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 and 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ma et al. (International Journal on Artificial Intelligence Tools (1999), pages 1-19), in view of Bailey et al. (Genome Research (1998) Vol. 8, pages 362-376).

In regard to claims 1-3 and 17-19, Ma et al. teach identification of promoters in unlabeled DNA sequences by classification using Bayesian networks (see abstract). The uncertainty about each neural network in this approach is taken into account by weighting the neural network by its posterior probability. The Bayesian neural network controls the model complexity to avoid the overfitting problem (page 1, line 31-page 2, lines 1-3). An approach to the method is to use a high-level features extracted from biosequences (annotations). The features should be relevant and biologically meaningful (page 2, paragraph 5).

The description of a Bayesian network, at page 9, section 3.1, describes the model consisting of a set of parameters viewed as random variables. A “prior”, a “likelihood” and a “posterior probability” are described which ultimately define Bayes Rule and meet the all of the limitations of instant claims 1-3 and 17-19.

Ma et al. do not specifically teach that the characteristic is the orientation of the biological sequence, that the cluster contains at least one EST, that evidence comprises poly-A/T tail analysis, inferred splice sites, and external sequences, or the testing of the null hypothesis to ascertain whether or not orientation is correct.

However, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to apply the data mining technique of Ma et al. to **any** biological characteristic of interest, such as sequence orientation. Furthermore, it would have been obvious to compile evidence from **any** sequence annotation information available. The motivation is supplied by Bailey et al. who define the state of the art in the analysis of EST-driven gene annotation. Bailey et al. even suggest that EST similarity searching is a practical general-purpose annotation technique that complements pattern recognition methods as a tool for gene

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characterization (see abstract). Ma et al. further motivates one to use the Bayesian approach for determining characteristics for any biological sequence classification scheme (page 1, abstract), as he states that the E. coli promoter recognition is just an example of this biological data mining tool.

No claims are allowed.

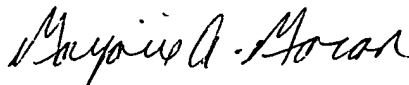
Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (571) 272-0549.


MARJORIE MORAN
PATENT EXAMINER

February 9, 2004

Lori A. Clow, Ph.D.

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